

OK TO ENTER

RX 7/19/04

Cosarczyk, Edward J.
U.S.S.N.: 09/778,125
Page 2 of 11

Amendments To The Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

1. (currently amended) A specimen collecting and testing device comprising:
an elongate, hollow housing having a proximal end and a distal end and a hollow portion;
at least one test membrane or sample collecting strip positioned within the hollow portion of the housing, the test membrane carrying diagnostic test chemistry;
a fluid chamber, for holding specimen, positioned adjacent to the test membrane or sample collecting strip;
at least one elongate handle member, having a proximal end and a distal end, slidably received in the hollow portion of the housing; and
a foam member, for collecting specimen, extending from the proximal end of the handle whereby, when the handle is drawn through the housing, collected specimen is deposited from the foam member into the fluid chamber and onto the test membrane or sample collecting strip,
wherein the housing includes a channel for receiving the handle member and foam member, and the fluid chamber is adjacent said channel.
2. (Original) The specimen collecting device of claim 1 further comprising an aperture in the fluid chamber through which specimen deposited in the fluid chamber passes onto the test membrane or sample collecting strip.
3. (Original) The specimen collecting and testing device of claim 1 further comprising a barrier or compression area on the proximal side of the fluid chamber, whereby, as the handle is drawn through the housing, the foam member contacts and is compressed by the barrier or compression area, thereby expelling specimen that is collected by the foam member into the fluid chamber.
4. (Original) The specimen collecting and testing device of claim 1, further comprising a barrier or compression area, whereby the barrier or compression area

Cesarczyk, Edward J.
U.S.S.N.: 09/778,125
Page 3 of 11

assists in extracting specimen of various viscosities from the foam member.

5. (Original) The specimen collecting and testing device of claim 4, wherein the barrier or compression area is V-shaped, U-shaped, straight, flat and/or chamfered.
6. (Original) The specimen collecting device of claim 1 further comprising a backup chamber, whereby specimen in excess to the capacity of the fluid chamber flows into the backup chamber.
7. (Original) The specimen collecting device of claim 1, wherein a barrier forms the distal side of the fluid chamber and prevents specimen deposited in the fluid chamber from flowing over or around the barrier onto the test membrane.
8. (Original) The specimen collecting device of claim 1 wherein a barrier forms the proximal end of the fluid chamber and is sized to meter the amount of specimen in the fluid chamber.
9. (Original) The specimen collecting and testing device of claim 1, wherein the elongate, hollow housing has an outer surface with at least one flat area, whereby, when the specimen collecting and testing device is placed on a surface, the at least one flat area prevents the specimen collecting and testing device from rolling.
10. (Original) The specimen collecting and testing device of claim 1, wherein the housing is made of plastic.
11. (Original) The specimen collecting and testing device of claim 1, wherein the foam member comprises a material selected from the group consisting of polyurethane foam, polyethylene foam, polyvinylchloride foam, ethylvinylacetate foam, polyethylene/ethylvinylacetate foam, polyester foam and polyether foam.
12. (Original) The specimen collecting and testing device of claim 11, wherein the foam member comprises a polyurethane foam.

Cesarczyk, Edward J.
U.S.S.N.: 09/778,125
Page 4 of 11

13. (Original) The specimen collecting and testing device of claim 1, wherein the handle member is hollow.
14. (Original) The specimen collecting and testing device of claim 13, wherein a portion of the foam member is disposed in the hollow handle member.
15. (Original) The specimen collecting and testing device of claim 1, wherein the handle member is made of paper or plastic.
16. (Original) The specimen collecting and testing device of claim 1, wherein the foam member extends from an end of the handle member a distance of about 25% to about 400% of a mean diameter of the handle or a mean diameter of an uncompressed cross sectional area of the foam member.
17. (Original) The specimen collecting and testing device of claim 1, wherein at least a portion of the housing comprises a transparent material such that the test membrane can be viewed through the portion of the housing.
18. (Original) The specimen collecting and testing device of claim 1, wherein at least a portion of the housing is removable, such that the test membrane or sample collecting strip can be viewed or removed through the removable portion of the housing.
19. (Original) The specimen collecting and testing device of claim 1, wherein at least a portion of the housing is open, such that the test membrane or sample collecting strip can be viewed through or removed through the open portion of the housing.
20. (Original) The specimen collecting and testing device of claim 1, wherein the at least one test membrane or sample collecting strip is removably positioned within the housing.

Cesarczyk, Edward J.
U.S.S.N.: 09/778,125
Page 5 of 11

21. (Original) The specimen collecting and testing device of claim 1 wherein the sample collecting strip is impregnated with preservatives.

22. (Original) A method of collecting a sample of fluid specimen for diagnostic testing, the method comprising:

providing a specimen collecting and testing device including:

an elongate, hollow housing having a proximal end and a distal end;

at least one test membrane or sample collecting strip positioned within the housing, the test membrane carrying diagnostic test chemistry;

a fluid chamber, for holding specimen, positioned adjacent to the test membrane or sample collecting strip;

an aperture in the fluid chamber positioned adjacent to the test membrane or sample collecting strip;

at least one elongate handle member, having a proximal end and a distal end, slidably received in the housing; and

a foam member, for collecting specimen, extending from the proximal end of the handle;

wetting the foam member with specimen;

positioning the device vertically with the foam member extending upwards;

sliding the handle member through the housing, thereby drawing the wetted foam member across the fluid chamber and delivering the collected specimen to the fluid chamber; and

positioning the device horizontally so as to level off the specimen in the fluid chamber and allow the specimen to flow through the aperture and onto the test membrane or sample collecting strip.

23. (Original) The method of claim 22, wherein the specimen collecting and testing device further comprises a barrier or compression area on the proximal side of the fluid chamber, the method further comprising compressing the foam member by the barrier or compression area, thereby expelling collected specimen which flows downwards into the fluid chamber.

Cesarczyk, Edward J.
U.S.S.N.: 09/778,125
Page 6 of 11

24. (Original) The method of claim 22, further comprising the step of removing the test membrane or sample collecting strip from the housing after the delivery of the specimen for further processing.

25. (Original) The method of claim 22, wherein the specimen collecting and testing device further includes a backup chamber proximate to the fluid chamber and wherein said step of positioning the device horizontally so as to level off the specimen in the fluid chamber further comprises allowing specimen in excess to the capacity of the fluid chamber to flow into the backup chamber.

26. (Previously presented) The specimen collecting and testing device of claim 1, wherein the elongate handle member is slidably received in the same hollow portion of the housing as the test membrane or sample collecting strip is positioned.

27. (Currently amended) A specimen collecting and testing device comprising:

a. a sample collecting mechanism comprising:

an elongate, hollow housing having a channel, a proximal end and a distal end and a hollow portion;

an elongate handle member slidably mounted within the channel ~~hollow portion of the housing~~;

a foam member for collecting specimen extending from the proximal end of the handle; and

c. a sample testing mechanism comprising:

at least one test membrane or sample collecting strip carrying diagnostic test chemistry positioned within the hollow portion of the housing; and

a fluid chamber, for holding specimen received from the foam member, within the hollow portion of the housing, the fluid chamber being adjacent to the channel and to the test membrane or sample collecting strip.

Cesarczyk, Edward J.
U.S.S.N.: 09/778,125
Page 7 of 11

28. (Previously presented) The specimen collecting and testing device of claim 27 further comprising a sample extraction mechanism comprising: the elongate hollow housing, whereby when the handle is drawn through the housing, collected specimen is extracted from the foam member and deposited onto the test membrane or sample collecting strip.
29. (Previously presented) The specimen collecting and testing device of claim 27, wherein the elongate handle member and housing are coaxial.
30. (Previously presented) A specimen collecting and testing device comprising:
an elongate, hollow housing having a proximal end and a distal end;
an elongate handle member having a proximal end and a distal end, the handle member slidably mounted within the housing;
the elongate handle member and housing being coaxial;
a foam member for collecting specimen extending from the proximal end of the handle;
at least one test membrane or sample collecting strip carrying diagnostic test chemistry positioned within the housing, and
a fluid chamber for holding specimen positioned adjacent to the test membrane or sample collecting strip, the fluid chamber having an aperture, whereby specimen collected by the foam member is deposited into the fluid chamber, through the aperture and onto the test membrane.
31. (Currently amended) A specimen collecting and testing device comprising:
an elongate, hollow housing having a channel, a proximal end and a distal end and a hollow portion;
at least one test membrane or sample collecting strip positioned within the hollow portion of the housing, the test membrane carrying diagnostic test chemistry;
a fluid chamber, for holding specimen, positioned adjacent the channel within the hollow portion of the housing and adjacent to the test membrane or sample collecting strip;

Cesarczyk, Edward J.
U.S.S.N.: 09/778,125
Page 8 of 11

at least one elongate handle member, having a proximal end and a distal end, slidably received in the channel ~~hollow portion~~ of the housing; and

a foam member, for collecting specimen, extending from the proximal end of the handle whereby, when the handle is drawn through the channel ~~housing~~, collected specimen is deposited from the foam member into the fluid chamber and onto the test membrane or sample collecting strip.

32. (Currently amended) A method of collecting a sample of fluid specimen for diagnostic testing, the method comprising:

providing a specimen collecting and testing device including:

an elongate, hollow housing having a channel, a proximal end and a distal end;

at least one test membrane or sample collecting strip positioned within the housing, the test membrane carrying diagnostic test chemistry;

a fluid chamber, sized for holding specific volumes of specimen, positioned adjacent to the channel and to the test membrane or sample collecting strip;

an aperture in the fluid chamber positioned adjacent to the test membrane or sample collecting strip;

at least one elongate handle member, having a proximal end and a distal end, slidably received in the channel ~~housing~~; and

a foam member, for collecting specimen, extending from the proximal end of the handle;

wetting the foam member with specimen;

positioning the device vertically with the foam member extending upwards;

sliding the handle member through the channel of the housing, thereby drawing the wetted foam member across the fluid chamber and delivering the collected specimen to the fluid chamber;

positioning the device horizontally so as to level off the specimen in the fluid chamber, and so as to allow specimen in excess of the volume of the fluid chamber to flow out of the fluid chamber; and

allowing the specimen in the fluid chamber to flow through the aperture and onto the test membrane or sample collecting strip.

Cesarczyk, Edward J.
U.S.S.N.: 09/778,125
Page 9 of 11

33. (Currently amended) A specimen collecting and testing device comprising:
- a. a sample collecting mechanism comprising:
 - an elongate, hollow housing having a channel, a proximal end and a distal end and a hollow portion;
 - an elongate handle member slidably mounted within the channel ~~hollow portion~~ of the housing;
 - a foam member for collecting specimen extending from the proximal end of the handle;
 - b. a sample holding and metering mechanism comprising:
 - a fluid chamber, for holding specimen, positioned adjacent to the channel and to the test membrane or sample collecting strip whereby, when the handle is drawn through the housing, collected specimen is deposited from the foam member into the fluid chamber prior to being deposited onto the test membrane or sample collecting strip; and
 - c. a sample testing mechanism comprising:
 - at least one test membrane or sample collecting strip carrying diagnostic test chemistry positioned within the hollow portion of the housing.
34. (Currently amended) A specimen collecting and testing device comprising:
- an elongate, hollow housing having a channel, a proximal end and a distal end;
 - an elongate handle member having a proximal end and a distal end, the handle member slidably mounted within the channel of the housing;
 - the elongate handle member and housing being coaxial;
 - a foam member for collecting specimen extending from the proximal end of the handle;
 - at least one test membrane or sample collecting strip carrying diagnostic test chemistry positioned within the housing, and
 - a fluid chamber for holding specimen positioned adjacent to the channel and to the test membrane or sample collecting strip, whereby specimen collected by the foam member is deposited into the fluid chamber, whereby the fluid chamber is sized so as to hold specific volumes of specimen, and whereby only the specific volume of specimen is deposited from the fluid chamber onto the test membrane.